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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Ronald Alan Coffee

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EXAMINER

SAMALA, JAGADISHWAR RAO

ART UNIT

PAPER NUMBER

1618

MAIL DATE

DELIVERY MODE

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/018,160	Applicant(s) COFFEE ET AL.	
	Examiner JAGADISHWAR R. SAMALA	Art Unit 1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 February 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 4,7-9,11,13-16,35,36,40-42,59,60,71-94 and 96-98 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 4,7-9,11,13-16,35-36,40-42,59-60,71-94 and 96-98 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Receipt is acknowledged of Applicant's Amendment and Remarks filed on 02/16/2009.

Claims 4, 7-9, 11, 13-16, 35-36, 40-41, 59-60, 71, 79, 85-86, 90 have been amended.

Claims 1-3, 5-6, 10, 12, 17-34, 37-39, 43-58, 61-70 and 95 have been cancelled.

Claims 96-98 have been added.

Claims 4, 7-9, 11, 13-16, 35-36, 40-42, 59-60, 71-94 and 96-98 are pending in the instant application.

Claim Rejections - 35 USC § 103

Claims 7-9, 11, 13-16, 34-40, 55, 58-60, 71-76, 78-83 and 85-95 are rejected under 35 U.S.C. 103(a) as being unpatentable over Coffee (WO 98/03267) and Roche et al (US 5,215,755) in view of Kovacs et al (US 5,322,698) **are withdrawn** in view of applicant's amendment to claims.

Claims 4-9, 11, 13-16, 34-38, 40-42, 55, 58-60 and 71-95 rejected under 35 U.S.C. 103(a) as being unpatentable over Coffee (WO 98/03267) and Roche et al (US 5,215,755) in view of Kovacs et al (US 5,322,698) as applied to claims 7-9, 11, 13-16, 34-40, 55, 58-60, 71-76, 78-83 and 85-95 above, and further in view of Hansen et al (US 6,423,346 B1) **are withdrawn** in view of applicant's amendment to claims.

However, upon further consideration, a new ground(s) of rejection is made as discussed below.

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1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

3. Claims 4, 7-9, 11, 13-16, 35-36, 40-42, 59-60, 71-94 and 96-98 are rejected under 35 U.S.C. 103(a) as being unpatentable over Coffee (WO-98/03267) in view of Liu et al (US 6,465,009) and Murray et al (US 6,709,669).

Coffee discloses processes and apparatuses for forming material by electrohydrodynamic comminution (Abstract; and page 4, lines 1-4). In one aspect, the processes and apparatuses disclosed within the document is capable of producing various solid and partially solid forms, such as fibers, fiber segments, fibrils, droplets, particles, webs, and mats. This formed matter may also contain a biologically active ingredient (page 2, line 12 to Page 3, Line 15). Fibers, fiber fragments, and particles of biologically active components for topical application such as analgesics, antiseptics, antibiotics, antifungals, antibacterials, antiparasitics, debridment agents, and biological material, such as fibrin or collagen may also be formed using the processes and

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apparatuses (page 5, lines 29-35 and 6, lines 13-18). Alternatively, the active ingredient may be provided as a coating or core of the fibers, fibrils, or particles or microcapsules (page 5, lines 7-28). Active ingredients may be supplied onto fibers, fibrils, or droplets in the form of a liquid that is dispensed through an outlet nozzle (page 22, lines 23- 33). The reference discloses that fibers have been successfully spun with polyhydroxybutyric acid, a resorbable polymer, and with polyvinyl alcohol, a water-soluble polymer (page 19, lines 20-23). In the formation of material provided by the methods and apparatuses disclosed in the reference, the supply of the material may be assisted by an air or inert gas flow (claim 32; and page 30, lines 27-31). When a melt is used as the material to be formed by the apparatuses and processes disclosed in the reference, the temperature of this material may be controlled by quenching using a cold air or inert gas stream (page 11, lines 17-22).

Coffee fails to disclose polysucrose and vinylpyrrolidone/vinylacetate copolymer in the process of manufacturing microcapsules.

Liu discloses formulation and method of manufacture of tablets comprising pharmaceutically active ingredient such as medicament, nutritional, palliative , drug and at least one water soluble non-saccharide polymer (polyvinylpyrrolidone). The tablets disintegrates rapidly or dissolves in about 1 to about 40 seconds in an aqueous solution, the tablet dissolves in the oral cavity and the aqueous solution is saliva (abstract and col. 2 lines 45-48). The polyvinylpyrrolidone can be vinylpyrrolidone-vinyl acetate copolymer (col. 2 lines 18-22). The tablet formulation comprises water soluble polymers as binder such as polyethylene glycol, gelatin, cellulose derivatives, saccharides such

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as mannitol, lactose, glucose, sucrose or a mixture thereof (col. 6 lines 1-20), disintegrants includes sodium starch glycolate, crossarmellose sodium and the like and sweetening agents (col. 8). Additional disclosure includes that tablet, when placed in the body cavity, rapidly disintegrates without the need for any co-application or ingestion of fluid. The ability to use a fast-disintegrating tablet without co-ingestion of water or other fluids allows for convenient administration of the tablet regardless of the age or condition of the individual, the time or the place.

Murray discloses a process for preparing fast-disintegrating dosage form comprising a carrier and an active ingredient (e.g. drug, compound and the like) wherein the carrier is fish gelatin and fast-dispersing dosage form releases the active ingredient rapidly on contact with a fluid (e.g., saliva, bodily fluids, water, and the like). Preferably, the composition is designed for oral administration (any other equivalent dosage form) and releases the active ingredient rapidly in the oral cavity (abstract and col. 3 lines 29-40). The composition also contain, in addition to the active ingredient and fish gelatin carrier, other matrix forming agents such as polysaccharides, carboxymethylcellulose, dextrans, synthetic polymers such as polyvinylpyrrolidone, polysaccharide complexes and sugars such as mannitol, dextrose, lactose, galactose (col. 5 lines 24-40). Additional disclosure includes that the composition can be contained in a mold during the freeze-drying process to produce a solid form in any desired shape.

It would have been obvious to the person of ordinary skill in the art at the time the invention was made to incorporate water soluble polymer such as vinylpyrrolidone-vinyl acetate copolymer and fish gelatin as binder into Coffee's method. The person of

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ordinary skill in the art would have been motivated to make those modifications, because vinylpyrrolidone-vinyl acetate copolymer and fish gelatin would assist in producing tablets with a better resistance to moisture and have adequate hardness, and reasonable would have expected success because both Coffee and cited reference teach process of manufacturing tablets that can be used in the same field of endeavor such as tablets which are advantageously hard, and dissolves rapidly in the oral cavity upon contact with saliva.

Claim limitations containing specific amounts of specific ingredients are considered by the examiner to be attainable by one of ordinary skill in the art through routine experimentation and are not considered to be critical. The amount of a specific ingredient and particle size in a composition is clearly a result effective parameter that a person of ordinary skill in the art would routinely optimize. It would have been customary for an artisan of ordinary skill to determine the optimal amount of each ingredient to add in order to best achieve the desired results of drug release. Thus, absent some demonstration of unexpected results from the claimed parameters, this optimization of ingredient amount would have been obvious at the time of Applicant's invention. Claims limitations, reciting specific moist tissue surfaces are considered by the examiner to be recitations of intended use, and thus do not carry patentable weight.

Conclusion

1. No claims are allowed at this time.
2. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JAGADISHWAR R. SAMALA whose telephone number is (571)272-9927. The examiner can normally be reached on 8.30 A.M to 5.00 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571)272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael G. Hartley/
Supervisory Patent Examiner, Art Unit 1618

Jagadishwar R Samala
Examiner
Art Unit 1618

sjr